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PATENT

Appl. No. 09/575,061

Amdt. dated March 8, 2005

Notice of Non-Compliant Amendment mailed March 2, 2005

Amendments to the Claims:

Please add new claims 14-22, and cancel claims 8-13. This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (previously presented) A method of diagnosing Crohn's disease in a subject, comprising determining the presence or absence of IgA anti-outer membrane protein C (anti-OmpC) antibodies in said subject, where the presence of said IgA anti-OmpC antibodies indicates that said subject has Crohn's disease.
2. (previously presented) A method of diagnosing Crohn's disease in a subject, comprising the steps of:
 - (a) obtaining a sample from a subject suspected of having inflammatory bowel disease;
 - (b) contacting the sample with an OmpC antigen, or reactive fragment thereof, under conditions suitable to form a complex of the OmpC antigen, or reactive fragment thereof, and IgA anti-OmpC antibody;
 - (c) contacting said complex with a labeled anti-IgA antibody to form a labeled complex; and
 - (d) detecting the presence or absence of said labeled complex, thereby determining the presence or absence of IgA anti-OmpC antibodies,where the presence of said IgA anti-OmpC antibodies in said subject indicates that said subject has Crohn's disease.

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3. (previously presented) A method of diagnosing Crohn's disease in a subject, comprising the steps of:

(a) contacting a sample from a subject suspected of having inflammatory bowel disease with an OmpC antigen, or reactive fragment thereof, under conditions suitable to form a complex of the OmpC antigen, or reactive fragment thereof, and IgA anti-OmpC antibody, wherein said OmpC antigen comprises the amino acid sequence of SEQ ID NO:1;

(b) contacting said complex with a labeled anti-IgA antibody to form a labeled complex; and

(c) detecting the presence or absence of said labeled complex, thereby determining the presence or absence of IgA anti-OmpC antibodies,

where the presence of said IgA anti-OmpC antibodies in said subject indicates that said subject has Crohn's disease.

4. (original) The method of claim 2, wherein IgA anti-OmpC antibodies are detected with an enzyme-linked immunosorbent assay.

5. (original) The method of claim 2, further comprising determining the presence or absence of IgA anti-Saccharomyces cerevisiae antibodies (ASCA) in said subject, wherein the presence of IgA anti-OmpC antibodies or the presence of IgA ASCA in said subject each independently indicates that said subject has Crohn's disease.

6. (original) The method of claim 5, wherein the presence of IgA ASCA is determined by reactivity with purified yeast cell wall phosphopeptidomannan (PPM).

7. (original) The method of claim 6, wherein said yeast cell wall PPM is prepared from ATCC strain #38926.

8.-13. (canceled)

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14. (new) A method of increasing the sensitivity of diagnosing Crohn's disease in a subject, comprising determining the presence or absence of IgA anti-OmpC antibodies in said subject, where the presence of said IgA anti-OmpC antibodies indicates ~~that~~ said subject has Crohn's disease.

15. (new) The method of claim 14, wherein the presence or absence of IgA anti-OmpC antibodies is detected in combination with detecting the presence or absence of ~~IgA~~ antibodies against one or more microbial antigens other than OmpC associated with Crohn's disease.

16. (new) The method of claim 15, wherein said one or more microbial antigens other than OmpC associated with Crohn's disease comprises IgA ASCA.

17. (new) A method of diagnosing Crohn's disease in a subject, comprising determining the presence or absence of IgA anti-OmpC antibodies and the presence or absence of IgA ASCA in said subject, where the presence of said IgA anti-OmpC antibodies and the presence of said IgA ASCA each independently indicate that said subject has Crohn's disease.

18. (new) A method of diagnosing Crohn's disease in a subject, comprising the steps of:

- (a) obtaining a sample from a subject suspected of having inflammatory bowel disease;
- (b) contacting the sample with an OmpC antigen, or reactive fragment thereof, and an one or more antigens specific for IgA ASCA under conditions suitable to form complexes of the OmpC antigen, or reactive fragment thereof, and IgA anti-OmpC antibody and the one or more antigens specific for ASCA and IgA ASCA;
- (c) contacting said complexes a labeled anti-IgA antibody to form labeled complexes; and

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(d) detecting the presence or absence of said labeled complexes, thereby determining the presence or absence of IgA anti-OmpC antibodies and the presence or absence of ASCA,

where the presence of said IgA anti-OmpC antibodies and the presence of ASCA in said subject each independently indicate that said subject has Crohn's disease.

19. (new) The method of any one of claims 14, 17 or 18, wherein IgA anti-OmpC antibodies and ASCA are detected with an enzyme-linked immunosorbent assay.

20. (new) The method of any one of claims 14, 17 or 18, wherein said OmpC antigen comprises the amino acid sequence of SEQ ID NO:1.

21. (new) The method of any one of claims 14, 17 or 18, wherein the presence of IgA ASCA is determined by reactivity with purified yeast cell wall phosphopeptidomannan (PPM).

22. (new) A method of diagnosing Crohn's disease in a subject, comprising determining the presence or absence of IgA anti-OmpC antibodies, IgA ASCA, IgA anti I-2 polypeptide antibodies and peri-nuclear anti-neutrophil antibodies (pANCA) in said subject, where the presence of said IgA anti-OmpC antibodies, IgA ASCA, IgA anti I-2 polypeptide antibodies and peri-nuclear anti-neutrophil antibodies (pANCA) in said subject indicates that said subject has Crohn's disease.

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